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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,561	09/19/2003	Richard A. Clark	064.00040	4600

35876 7590 08/27/2007

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EXAMINER	
PERREIRA, MELISSA JEAN	
ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
08/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/664,561	CLARK ET AL.	
	Examiner	Art Unit	
	Melissa Perreira	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,9-12 and 17-21* is/are pending in the application.

4a) Of the above claim(s) *1 and 3* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-12 and 17-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/15/07 has been entered.

2. Claims 1,3,9-12 and 17-21 are pending in the application. Claims 1 and 3 are withdrawn from consideration. Claims 18-21 are newly added in the amendment filed 4/16/07.

Oath/Declaration

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 9,10,12,17 and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Pines et al. (US 5,330,974).

5. Pines et al. (US 5,330,974) teaches of a composition comprising fibrinogen and fatty acids where fatty acids are lipid building blocks as evidenced by the PTO-892 BIO 113 document (column 2, lines 61-63; column 10, line 9). Up to about 95%, or greater, of the total protein present in the composition is fibrinogen (column 5, lines 37-38). When applied to wounds, polymerized fibrinogen forms a network or scaffolding through which it is more likely that immunologically active cells (to defend against invading pathogens) and also epithelial cells (for tissue regeneration and repair) can migrate (column 1, lines 40-45). The composition of the disclosure encompasses the composition of the instant claims and therefore should be capable of the same functions and properties, such as enhance fibroblast migration. Also, The intended use of the composition for wound healing is not afforded any patentable weight. "The recitation of a new intended use for an old product does not make a claim to that old product patentable." *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997).

6. It is respectfully pointed out that instant claims 12 and 17 are product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 9-12 and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacPhee et al. (US 6,117,425) in view of Pines et al. (US 5,330,974).

9. MacPhee et al. (US 6,117,425) discloses a composition of matter that promotes wound healing comprising lipids and fibrinogen (column 8, line 67+; claim 1). MacPhee et al. does not disclose the purification of the instant claims.

10. Pines et al. (US 5,330,974) teaches of a composition comprising fibrinogen and fatty acids as well as that taught above.

11. At the time of the invention it would have been obvious to one skilled in the art to prepare purified of about 99% fibrinogen compositions containing lipids for wound healing as they both perform the same function. It would also be advantageous to optimize the purification to reduce adverse immune response. The composition of the disclosures do not exclude plasma lipids.

12. It is respectfully pointed out that instant claims 12 and 17 are product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-

by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

13. Claims 9-12 and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wadstrom (US 5,631,011) in view of Zaloga et al. (US 5,656,588) in further view of Pines et al. (US 5,330,974).

14. Wadstrom (US 5,631,011) discloses a tissue treatment composition comprising fibrinogen (abstract; column 3, lines 15-16). In regards to wound healing, the fibrinogen promotes ingrowth of fibroblasts which in combination with efficient hemostasis and adhesion between the wound surfaces provides for an improved healing process (column 1, lines 64-67). Wadstrom does not disclose the inclusion of a lipid in the tissue treatment composition.

15. Zaloga et al. (US 5,656,588) discloses that one of the steps of the pathophysiology of wound healing includes fibroblast proliferation (column 1, lines 25-28). The composition for stimulating wound healing comprises a lipid source (column 2, lines 58-63).

16. Pines et al. (US 5,330,974) teaches of a composition comprising fibrinogen and fatty acids as well as that taught above.

17. At the time of the invention it would have been obvious to one skilled in the art to utilize a lipid from the wound healing composition of Zaloga et al. in the tissue treatment composition of Wadstrom as they are directed toward the same function. In view of the

reference of Pines et al. it is known in the art that compositions for wound healing contain both fibrinogen and fatty acids. It would be predictable that the combined composition of Wadstrom and Zaloga et al. provides wound healing and can be purified (Pines et al.) to provide fibrinogen with purity of about 99%. It would also be advantageous to optimize the purification to reduce adverse immune response. The composition of the disclosures do not exclude plasma lipids.

18. It is respectfully pointed out that instant claims 12 and 17 are product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP
July 27, 2007

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER